

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

ON APPEAL FROM THE PRIMARY EXAMINER TO THE
BOARD OF PATENT APPEALS AND INTERFERENCES

Inventor : Lattner et al.
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Title : INTRAORAL ELECTROMUSCULAR STIMULATION DEVICE AND METHOD
Examiner : Thomas, Jonathan B.
Group Art Unit : 3709
Attorney Docket No. : 98-15 D1

MAIL STOP APPEAL BRIEF – PATENTS
Commissioner for Patents
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APPEAL BRIEF UNDER 37 C.F.R. §41.37

Sir:

This Appeal Brief is submitted in support of the Notice of Appeal mailed 15 February 2008. This Appeal Brief provides the authorities and arguments upon which Applicant relies to reverse the rejection of claims 43 - 58 and 60 of the above-identified patent application. The rejection of claims 43 - 58 and 60 are set forth in the Final Office Action dated 28 September 2007. The headings used hereinafter, and that which is set forth under each heading, are presented in accordance with 37 C.F.R. §41.37(c).

CERTIFICATE OF AUTHORIZATION/ELECTRONIC FILING

This paper (along with any referred to as being attached or enclosed) is being electronically filed with the U.S. Patent and Trademark Office by the undersigned agent/attorney of record on 18 March 2008.

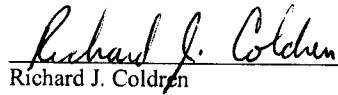

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I. REAL PARTY IN INTEREST

The real party in interest for the above-identified patent application is RIC Investments, LLC. This interest arises via an assignment from the inventors to Respiromics, Inc., via an assignment from Respiromics, Inc. to RIC Investments, Inc., and via an assignment from RIC Investments, Inc. to RIC Investments, LLC. The assignment between the inventors and Respiromics, Inc. was recorded on 9 November 1999 at reel/frame 010391/0896. The assignment between Respiromics, Inc. and RIC Investments, Inc. was recorded on 7 November 2005 at reel/frame 016741/0570. The assignment between RIC Investments, Inc. and RIC Investments, LLC was recorded on 8 November 2005 at reel/frame 016747/0177. RIC Investments, LLC and RIC Investments, Inc. are subsidiaries of Respiromics, Inc., which is a wholly owned subsidiary of Philips Holding USA, Inc.

II. RELATED APPEALS AND INTERFERENCES

There are no appeals or interferences, known to the Applicant, the Applicant's undersigned legal representative, or the Assignee, which will directly affect, or be directly affected by, or have a bearing on, the Board's decision in this Appeal.

III. STATUS OF CLAIMS

Claims 43 - 58 and 60 are pending and are appealed.

Claims 43 - 47, 49 - 54, and 56 stand rejected pursuant to 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 5,190,053 to Meer (i.e., “Meer”) in view of U.S. Patent No. 5,365,945 to Halstrom (i.e., “Halstrom”).

Claims 48 and 55 stand rejected pursuant to 35 U.S.C. § 103(a) as allegedly being unpatentable over Meer in view of Halstrom, and in further view of U.S. Patent No. 4,414,982 to Durkan (i.e., “Durkan”).

Claims 57, 58, and 60 stand rejected pursuant to 35 U.S.C. § 103(a) as allegedly being unpatentable over Meer in view of *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (i.e., “Aller”).

A listing of the pending claims is provided in Appendix A attached hereto.

IV. STATUS OF AMENDMENTS

All amendments to the claims in this application have been entered. The claims on appeal include the latest changes submitted by Applicant's Amendment dated 17 September 2007. Each of the pending claims was finally rejected in an Office Action mailed on 28 September 2007.

V. SUMMARY OF CLAIMED SUBJECT MATTER

All of the pending claims (claims 43 - 58 and 60) are involved in this appeal. The following is a concise explanation of the subject matter set forth in claims 43 - 46, 48, 50 - 53, 55, 57 - 58, and 60.

An embodiment of the claimed subject matter, as recited in claim 43, is best understood with reference to Figures 9A and 9B. Claim 1 recites a system for treating a breathing disorder that comprises an electromuscular stimulating means for providing electrical energy to a sublingual location of a patient and a mandibular positing means for controlling a position of such a patient's mandible relative to an upper dentition of such a patient. (See specification page 41, line 3 through page 43, line 21; *see also, for example*, page 11, line 16 to page 12, line 20.)

Claim 44 depends from claim 43. As such, claim 44 includes the subject matter recited by claim 43 as discussed above, and further recites wherein the electromuscular stimulating means includes positioning means for locating a first electrode and a second electrode in sublingual positions within a patient's oral cavity such the second electrode is located in a position posterior to the first electrode to deliver the electrical energy in an anterior-to-posterior direction or a posterior-to-anterior direction. (*Id.* at page 43, lines 14 - 21 and page 24, lines 4 - 19.)

Claim 45 depends from claim 44. As such, claim 45 includes the subject matter recited by claims 43 and 44 as discussed above, and further recites wherein the electromuscular stimulating means includes positioning means for locating a first electrode and a second electrode on a same side of a patient's oral cavity. (*Id.* at page 43, lines 14 - 21.)

Claim 46 depends from claim 43. As such, claim 46 includes the subject matter recited by claim 43 as discussed above, and further recites wherein the electromuscular stimulating means includes positioning means for locating a first electrode and a second electrode posterior to the frenulum. (*Id.* at page 14, lines 1 - 3.)

Claim 48 depends from claim 43. As such, claim 48 includes the subject matter recited by claim 43 as discussed above, and further recites that the system further comprises a means for

providing a positive pressure to an airway of such a patient. (*Id.* at page 39, lines 14 - 16; *see also* Figures 8A and 8B.)

An embodiment of the claimed subject matter, as recited in claim 50, is best understood with reference to Figures 9A and 9B. Claim 50 recites a method of treating a breathing disorder comprising providing electrical energy to a sublingual location of a patient and controlling a position of such a patient's mandible relative to an upper dentition of such a patient. (*See* specification page 41, line 3 through page 43, line 21; *see also, for example*, page 11, line 16 to page 12, line 20.)

Claim 51 depends from claim 50. As such, claim 51 includes the subject matter recited by claim 50 as discussed above, and further recites wherein providing electrical energy includes positioning a first electrode and a second electrode in sublingual positions within such a patient's oral cavity such that the second electrode is located in a position posterior relative to the first electrode, and applying an electrical stimulation via the first electrode and the second electrode so as to deliver electrical energy to a patient in an anterior-to-posterior direction or a posterior-to-anterior direction. (*Id.* at page 43, lines 14 - 21 and page 24, lines 4 - 19.)

Claim 52 depends from claim 50. As such, claim 52 includes the subject matter recited by claim 50 as discussed above, and further recites wherein providing electrical energy includes locating a first electrode and a second electrode on a same side of a patient's oral cavity. (*Id.* at page 43, lines 14 - 21.)

Claim 53 depends from claim 50. As such, claim 53 includes the subject matter recited by claim 50 as discussed above, and further recites wherein providing electrical energy includes locating a first electrode and a second electrode posterior to the frenulum. (*Id.* at page 14, lines 1 - 3.)

Claim 55 depends from claim 50. As such, claim 55 includes the subject matter recited by claim 50 as discussed above, and further comprises providing a positive pressure to an airway of such a patient. (*Id.* at page 39, lines 14 - 16; *see also* Figures 8A and 8B.)

Claim 56 depends from claim 50. As such, claim 56 includes the subject matter recited by claim 50 as discussed above, and further recites wherein providing electrical energy includes detecting an inspiratory phase and an expiratory phase of a patient, and controlling delivery of electrical energy such that electrical stimulation occurs at a stimulation start time prior to onset

of the inspiratory phase and continues through at least a portion of the inspiratory phase. (*Id.* at page 19, line 18 to page 20, line 2 and page 27, line 11 to page 29, line 8.)

An embodiment of the claimed subject matter, as recited in claim 57, is best understood with reference to Figures 9A and 9B, and as described by the specification on page 41, line 3 through page 43, line 21. Claim 57 recites an intraoral electromuscular stimulation device adapted to provide intraoral electrical stimulation to a patient. The stimulation device comprises a first electrode, a first support member adapted to support the first electrode in a sublingual location within a patient's oral cavity, a second electrode, a second support member adapted to support the second electrode in a sublingual location within such a patient's oral cavity, wherein the first support member and the second support member are configured and arranged such that the second electrode is disposed in a position posterior relative to the first electrode, a sensor adapted to detect a respiratory parameter of such a patient and to output a signal indicative thereof, and a control unit operatively coupled to the sensor, the first electrode and the second electrode, wherein the control unit (1) receives the signal from the sensor and distinguishes between inspiration and expiration of such a patient based thereon, (2) initiates an electrical stimulation of such a patient in an anterior-to-posterior or posterior-to-anterior direction via the first and the second electrodes at a stimulation start time between 100-200 ms prior to onset of inspiration, and (3) continues stimulation through at least a portion of inspiration. (*Id.* at page 41, line 3 through page 43, line 21; page 11, line 16 to page 12, line 20; page 19, line 18 to page 20, line 2 and page 27, line 11 to page 29, line 8; page 43, lines 14 - 21 and page 24, lines 4 - 19; page 43, lines 14 - 21.)

Claim 58 depends from claim 57. As such, claim 58 includes the subject matter recited by claim 57 as discussed above, and further recites wherein the first support member and the second support member are coupled to one another. (*Id.*)

An embodiment of the claimed subject matter, as recited in claim 60, is best understood with reference to Figures 9A and 9B, and as described by the specification on page 41, line 3 through page 43, line 21. Claim 60 recites an intraoral electromuscular stimulation device adapted to provide intraoral electrical stimulation to a patient. The stimulation device comprises a first electrode, a first support member adapted to support the first electrode in a sublingual location within a patient's oral cavity posterior to a frenulum and generally proximate to one of a

first molar, a second molar, and a third molar of such a patient, a second electrode, a second support member adapted to support the second electrode in a sublingual location within such a patient's oral cavity and posterior relative to the first electrode, wherein the first support member and the second support member are configured and arranged such that the second electrode is disposed in a position posterior relative to the first electrode, a sensor adapted to detect a respiratory parameter of such a patient and to output a signal indicative thereof, and a control unit operatively coupled to the sensor, the first electrode and the second electrode, wherein the control unit (1) receives the signal from the sensor and distinguishing between inspiration and expiration of such a patient based thereon, (2) initiates an electrical stimulation of such a patient in an anterior-to-posterior or posterior-to-anterior direction via the first and second electrodes at a stimulation start time prior to onset of inspiration, and (3) continues stimulation through at least a portion of inspiration. (*Id.* at page 41, line 3 through page 43, line 21; page 11, line 16 to page 12, line 20; page 19, line 18 to page 20, line 2 and page 27, line 11 to page 29, line 8; page 43, lines 14 - 21 and page 24, lines 4 - 19; page 43, lines 14 - 21.)

Claims 47, 49, 54, and 56 are not argued separately in this Appeal. Therefore, Appellant is not required to provide a concise explanation of any dependent claim pursuant to 37 C.F.R. § 41.37(c)(1)(v).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

- A. Whether claims 43 - 47, 49 - 54, and 56 were properly rejected under 35 U.S.C. § 103(a) as being unpatentable over Meer in view of Halstrom?
- B. Whether claims 48 and 55 were properly rejected under 35 U.S.C. § 103(a) as being unpatentable over Meer in view of Halstrom and in further view of Durkan?
- C. Whether claims 57 - 58, and 60 were properly rejected under 35 U.S.C. § 103(a) as being unpatentable over Meer in view of *Aller*?

VII. ARGUMENT

When making a rejection under 35 U.S.C. § 103(a), the Examiner has the burden of establishing a *prima facie* case of obviousness. *In re Fritch*, 23 U.S.P.Q.2d 1780, 1783 (Fed. Cir. 1992). Establishing a *prima facie* case of obviousness first requires the Examiner to resolve the factual inquires set forth in the case of *Graham v. John Deere Co.*, 383 U.S. 1, 148 U.S.P.Q. 459 (1966). These inquires include: (1) determining the scope and content of the prior art, (2) ascertaining the differences between the claimed invention and the prior art, and (3) resolving the level of ordinary skill in the pertinent art. (*Id.* at 17.) Upon completing this analysis, the Examiner must then prove that, despite the differences between the prior art and the claimed invention, one skilled in the art would find it obvious to modify or combine the prior art in order to create the claimed invention. *KSR Int'l Co., v. Teleflex Inc.*, 127 S. Ct. 1727, 1741; 82 U.S.P.Q.2d at 1396 (2007).

1. Scope and Content of the Prior Art

Meer

Meer discloses an intra-oral, sublingual electrode device for the electrical stimulation of a user's genioglossus muscle for the treatment of sleep apnea. (See Meer at column 1, lines 6 - 8.) The Meer device has a first electrode (12) and a second electrode (14) supported by a support means (16). (*Id.* at column 4, lines 19 - 22.) The electrodes are arranged such that, when placed in a user's mouth, the first electrode (12) is in contact with a user's sublingual mucosa on one side of the user's frenulum and the second electrode is in contact with the user's sublingual mucosa on the opposite side of the user's frenulum. (*Id.* at column 4, lines 38 - 47.) A pulse generator (52) is used to provide electrical pulses to the first (12) and second (14) electrodes. (*Id.* at column 6, lines 29 - 32.) Meer teaches that "the polarity of the electrical pulses is periodically reversed according to predetermined criteria so that electrical current flows through the genioglossus muscle in both directions to ensure a balanced stimulation of both sides of the genioglossus muscle. (*Id.* at column 6, lines 34 - 39.) Because the first (12) and second (14) electrodes are placed on opposite sides of the frenulum, the genioglossus muscle is stimulated laterally (i.e., from one side of the genioglossus muscle to the other side of the genioglossus muscle). Meer asserts that this sublingual electrical stimulation device provides additional

advantages over prior art procedures and/or devices. (*Id.* at column 2, lines 18 - 22.) Notably, Meer teaches that sublingual electrical stimulation is an improvement over mandibular advancement devices. Specifically, Meer states that mandibular advancement devices (e.g., jaw positioners) "are inconvenient, cumbersome and uncomfortable, which makes their continued use for long periods unlikely". (*Id.* at column 1, lines 50 - 55.)

Halstrom

Halstrom discloses a dentally retained intra-oral appliance for the treatment of snoring and sleep apnea. (*See* Halstrom at column 1, lines 7 - 11.) The appliance maintains a patient's mandible in an anterior, protruded position relative to the patient's maxilla. (*Id.*) The appliance is comprised of an upper bite block (28), a lower bite block (32), and a connecting assembly (40). (*Id.* at column 5, lines 6 - 21.) The upper bite block (28) is shaped to conform to the user's maxillary dentition; whereas the lower bite block (32) is shaped to conform to the user's mandibular dentition. (*Id.*) The connecting assembly (40) releasably couples the upper bite block (28) to the lower bite block (32) in such a manner as to control the anterior alignment of the lower bite block (32) relative to the upper bite block (28) and/or the degree of opening of the jaw. (*Id.* at column 6, lines 53 - 68; *see also* column 7, lines 27 - 43.) Halstrom asserts that this dental appliance is an improvement over prior art dental appliances because it maintains "the mandible in the preferred anterior position", but also allows a limited degree of lateral movement "to avoid discomfort to the tempromandibular joint and related muscles and ligaments". (*Id.* at column 2, lines 33 - 39.)

Durkan

Durkan discloses a respirator apparatus for providing intermittent demand oxygen flow and/or for detecting apneic events. (*See* Durkan at column 1, lines 5 - 9.) Durkan discloses that a nasal cannula, nasal prongs, or a mask may be used to deliver breathing gas to a patient. (*Id.* at column 3, lines 54 - 58.) Durkan, however, fails to teach or suggest that the breathing gas can be delivered via an oral appliance. Durkan states that prior art intermittent demand oxygen devices, whether sensing negative or positive pressure, supply oxygen to a patient substantially throughout the duration of an inspiration. (*Id.* at column 1, lines 36 - 39.) In contrast, the device disclosed in Durkan provides a greater volume of oxygen per minute (albeit for a shorter duration) at an early stage of inspiration, thus reducing the amount of oxygen that is wasted. (*Id.*

at column 8, lines 42 - 55.) Durkan teaches that apparatus includes an apneic event circuit (10) which detects when a patient stops breathing and activates one or more alarm signals. (*Id.* at column 13, line 61 - column 14, line 15.) Durkan, however, fails to teach or suggest that the operation of the respirator apparatus is changed in any manner in response to detecting an apneic event.

2. Differences Between the Prior Art and the Claimed Invention

The claimed invention is generally directed to treating breathing disorders using an intraoral dental appliance (160) capable of providing both electromuscular stimulation and mandibular positioning. (See Specification at page 41, lines 3 - 7; *see also* Figures 9A and 9B.) In one embodiment, the appliance includes a mouthpiece (162) having an upper member (164) that attaches to the patient's upper teeth and a lower member (166) that attaches to the patient's lower teeth. (*Id.* at page 41, lines 18 - 21.) A mechanical linkage (176) couples upper member (164) and lower member (166) to one another and controls the anterior/posterior positioning of the upper member (164) relative to the lower member (166). (*Id.* at page 42, line 5 to page 43, line 3.)

A pair of electrode supports (144) extends from the mouthpiece (162). (*Id.* at page 43, lines 14 - 21.) The electrode supports (144) are structured to position a number of electrodes (146) against the floor of the patient's mouth posterior to the frenulum during use. (*Id.* at page 40, lines 6 - 13.) At least two electrodes (146) are disposed on each electrode support (144), and accordingly, the at least two electrodes (146) are located on the same side of a patient's oral cavity when the mouthpiece is inserted into the patient's mouth. (*Id.* at page 36, line 17 to page 37, line 2.) With such an arrangement, stimulation pulses applied to the electrodes (146) propagate in an anterior-to-posterior or a posterior-to-anterior direction. (*Id.* at page 24, lines 4 - 19.) The intraoral dental appliance (106) may also be adapted to supply a positive pressure flow of breathing gas to a patient. (*Id.* at page 38, lines 15 - 17; *see also* page 39, lines 14 - 16 and page 44, lines 1 - 6.) In one embodiment, an orifice (138) provides a channel for communicating breathing gas from an external breathing gas source to the airway of the patient. (*Id.* at page 39, lines 14 - 16; *see also* Figures 8A and 8B.)

3. The Level of Ordinary Skill in the Pertinent Art

A person of ordinary skill in the art is a hypothetical person who is presumed to have the relevant art at the time of the invention. Factors that may be considered in determining the level of ordinary skill in the art may include: (1) "type of problems encountered in the art"; (2) "prior art solutions to those problems"; (3) "rapidity with which innovations are made"; (4) sophistication of the technology"; and (5) "educational level of active workers in the field". In a given case, every factor may not be present, and one or more factors may predominate. *In re GPAC*, 57 F.3d 1573, 1579 (Fed. Cir. 1995); *Custom Accessories, Inc. v. Jeffrey-Allan Indus., Inc.*, 807 F.2d 955, 962 (Fed. Cir. 1985); *Envil. Designs, Ltd. v. Union Oil Co.*, 713 F.2d 693, 696 (Fed. Cir. 1983).

Here, it is believed that a person of ordinary skill in the art would be familiar with using electromuscular stimulation (for example as taught by Meer), mandibular advancement (for example as taught by Halstrom), or the delivery of breathing gas to a patient's airway (for example as taught by Durkan) for treating breathing disorders.

4. The Final Office Action Fails to Support the Rejection of Claim Under 35 U.S.C. § 103(a)

In order for an invention to be properly rejected under 35 U.S.C. § 103(a), there must be an explicit rationale explaining why, despite the differences between the applied art and the claimed invention, the claimed invention would have been obvious to one of ordinary skill in the art. *KSR Int'l Co., v. Teleflex Inc.*, 127 S. Ct. 1727, 1741; 82 U.S.P.Q.2d at 1396 (2007). As will be discussed in detail below, the Examiner has failed to provide adequate support as to why a person of ordinary skill would find it obvious to combine the device for providing electromuscular stimulation as taught by Meer, with the device for providing mandibular positioning as taught by Halstrom, and/or with the apparatus for providing intermittent demand oxygen flow and detecting apneic events as taught by Durkan.

Additionally, the Examiner has failed to consider the cited references in their entirety. Specifically, the Examiner has ignored those portions of Meer which teach away from combination with Halstrom. The prior art reference should be considered as a whole, and

portions arguing against or teaching away from the claimed invention must be considered. *Bausch & Lomb, Inc. v. BarnsHind/Hydrocurve, Inc.*, 230 U.S.P.Q. 416 (Fed. Cir. 1986). A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Associates v. Garlock, Inc.*, 721 F.2d 1540, 200 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984). “When the prior art teaches away from combining certain known elements, discovery of successful means of combining them is more likely to be nonobvious.” *KSR International, Inc. v. Teleflex, Inc.*, 127 S. Ct. 1727, 1740, 167 L. Ed. 2d 705, 721 (2007). (*See also* MPEP 2141.02 VI.)

The Examiner also fails to provide support as to why one of ordinary skill in the art would be motivated to combine the teachings of the cited references. The Examiner merely concludes that because each of the devices/methods taught in the references are related to the treatment of breathing disorders, that one skilled in the art would be motivated to combine these devices/methods. However, the mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification. *See, In re Fritch*, 972 F.2d 1260, 23 U.S.P.Q.2d 1780 (Fed. Cir. 1992). The fact that elements of the claimed invention exist in the known art does not by itself provide the motivation to make the claimed invention. *See, e.g., In re Newell*, 13 U.S.P.Q.2d 1248 (Fed. Cir. 1989). Furthermore, even the mere fact that the prior art teachings *can* be combined does not support a rejection based on these references. *See, e.g., In re Fitch*, 972 F.2d 1260, 23 U.S.P.Q.2d 1780 (Fed. Cir. 1992).

The Examiner has also failed to appreciate that posterior-to-anterior and/or anterior-to-posterior stimulation as used in the claimed invention is different from lateral stimulation as taught in Meer. In contrast, the Examiner has reached the unsupported conclusion that posterior-to-anterior and/or anterior-to-posterior stimulation is merely an “optimum or workable range” of lateral stimulation.

For these reasons, the rejections of claims 43 - 58, and 60 should be reversed.

A. Rejection Under 35 U.S.C. 103(a) over U.S. Patent Number 5,190,053 to Meer in view of U.S. Patent Number 5,365,945 to Halstrom.

The Examiner has rejected claims 43 - 47, 49 - 54, and 56 as being unpatentable over Meer in view of Halstrom. Applicant respectfully submits that the Examiner has failed to prove that, despite the differences between the prior art and the claimed invention, one skilled in the art would find it obvious to modify or combine the prior art in order to create the invention recited in claims 43 - 47, 49 - 54, and 56. It is submitted that the Examiner has failed to consider Meer as a whole, and more specifically, has failed to consider the portions of Meer which argue against and/or teach away from combining sublingual electrical stimulation with mandibular advancement. For these reasons, it is requested that the rejection of claims 43 - 47, 49 - 54, and 56 be reversed.

Claim 43

Claim 43 recites a system for treating a breathing disorder comprising an electromuscular stimulating means and a mandibular positioning means. As discussed above, Meer discloses an intra-oral, sublingual electrode device for the electrical stimulation of a genioglossus muscle for the treatment of sleep apnea. As noted by the Examiner, however, Meer fails to teach a mandibular positioning device.

The Examiner concluded that it would have been obvious to one skilled in the art to combine the intra-oral, sublingual electrode device as taught by Meer with the intra-oral appliance as taught by Halstrom. In contrast to the Examiner's position, Meer teaches away from such a combination. The stated object of Meer is to treat breathing disorders using a sublingual stimulation device which overcomes the disadvantages of prior art devices (such as the disadvantages of prior art mandibular positioning devices). (Meer at column 2, lines 18 - 22.) Meer specifically states "weight reduction and the use during sleeping hours of various devices, such as airways and tongue and jaw positioners, have been partially effective; but these measures are inconvenient, cumbersome and uncomfortable, which makes their continued use for long periods unlikely." (*Id.* at column 1, lines 50 - 55; emphasis added.)

Because Meer teaches that jaw positioners are "inconvenient, cumbersome and uncomfortable" and that continued patient compliance for these devices is unlikely, it is respectfully submitted that one of ordinary skill in the art would not be inclined to combine the Meer electrical sublingual stimulation device with the Halstrom intra-oral appliance. Such a combination would increase the bulk of Meer's stimulation device making it "inconvenient,

“cumbersome and uncomfortable” and decreasing patient compliance with the device. For these reasons, the rejection of claim 43 pursuant to 35 U.S.C. § 103(a) should be withdrawn.

Claim 44

Claim 44 depends from allowable claim 43. Thus, claim 44 is believed to be allowable for the reasons discussed above in conjunction with claim 43. Claim 44 further recites that the electromuscular stimulating means “includes positioning means for locating a first electrode and a second electrode in sublingual positions within a patient’s oral cavity such that the second electrode is located in a position posterior to the first electrode to deliver the electrical energy in an anterior-to-posterior direction or a posterior-to-anterior direction.”

In contrast, Meer teaches that a first electrode (12) is in contact with a user’s sublingual mucosa on one side of the user’s frenulum and a second electrode (14) is in contact with the sublingual mucosa on the opposite side of the frenulum. (Meer at column 4, lines 38 - 47.) As such, electrical stimulation pulses applied to the Meer electrodes stimulates the genioglossus muscle laterally (i.e., from one side of the genioglossus muscle to the other side of the genioglossus muscle).

Meer fails to teach or suggest locating the second electrode posterior to the first electrode. Accordingly, the Meer device cannot apply electrical stimulation in a posterior-to-anterior and/or anterior-to-posterior direction. Halstrom also fails to provide any teaching related to electrical stimulation. It is respectfully submitted that the Examiner has failed to provide any support as to why one of ordinary skill in the art, considering the teachings of Meer and Halstrom, would arrive at a device for delivering electrical stimulation in the anterior-to-posterior and/or the posterior-to-anterior directions. For these reasons, the rejection of claim 44 pursuant to 35 U.S.C. § 103(a) should be withdrawn.

Claim 45

Claim 45 depends from allowable claim 43. Thus, claim 45 is believed to be allowable for the reasons discussed above in conjunction with claim 43. Claim 45 further recites “wherein the electromuscular stimulating means includes positioning means for locating a first electrode and a second electrode on a same side of a patient’s oral cavity.” As discussed above, Meer not

only fails to suggest locating the first and second electrodes on the same side of a patient's oral cavity, but instead, Meer directly teaches away from such an arrangement. Specifically, Meer teaches locating the first electrode on one side of the oral cavity (i.e., in contact with a user's sublingual mucosa on a first side of the user's frenulum) and the second electrode on the opposite side of the oral cavity (i.e., in contact with the sublingual mucosa on the opposite side of the frenulum). (Meer at column 4, lines 38 - 47.) Halstrom fails to provide any teaching related to electrode placement. For these reasons, the rejection of claim 45 pursuant to 35 U.S.C. § 103(a) should be withdrawn.

Claim 46

Claim 46 depends from allowable claim 43. Thus, claim 46 is believed to be allowable for the reasons discussed above in conjunction with claim 43. Claim 46 further recites "wherein the electromuscular stimulating means includes positioning means for locating a first electrode and a second electrode posterior to the frenulum." As discussed above, Meer teaches locating the first electrode in contact with a user's sublingual mucosa on one side of the user's frenulum and the second electrode in contact with the sublingual mucosa on the opposite side of the frenulum. Because Meer teaches locating the electrodes on both sides of the frenulum, and because Halstrom fails to provide any teaching related to electrode placement, it is respectfully submitted that one skilled in the art would not have located the electrodes posterior to the frenulum. For these reasons, the rejection of claim 46 pursuant to 35 U.S.C. § 103(a) should be withdrawn.

Claim 47

Claim 47 depends from allowable claim 43. Thus, claim 47 is believed to be allowable for the reasons discussed above in conjunction with claim 43. Accordingly, the rejection of claim 47 pursuant to 35 U.S.C. § 103(a) should be withdrawn.

Claim 49

Claim 49 depends from allowable claim 43. Thus, claim 49 is believed to be allowable for the reasons discussed above in conjunction with claim 43. Accordingly, the rejection of claim 49 pursuant to 35 U.S.C. § 103(a) should be withdrawn.

Claim 50

Claim 50 recites a method of treating a breathing disorder. The method comprises providing electrical energy to a sublingual location of a patient, and controlling a position of such a patient's mandible relative to an upper dentition of such a patient. The Examiner rejected claim 50 "because the apparatus of Meer in view of Halstrom as applied to claims 43 - 47, and 49 above performs the method steps as claimed".

As discussed above in conjunction with claim 43, one of ordinary skill in the art would not find it obvious to combine the teachings of Meer with the teachings of Halstrom to obtain a system for treating a breathing disorder comprising an electromuscular stimulating means and a mandibular positioning means. For the same reasons discussed above in conjunction with claim 43, it is believed that one of ordinary skill in the art would not find it obvious to combine the teachings of Meer and Halstrom to obtain the method recited by claim 50. Accordingly, the rejection of claim 50 pursuant to 35 U.S.C. § 103(a) should be withdrawn.

Claim 51

Claim 51 depends from allowable claim 50. Thus, claim 51 is believed to be allowable for the reasons discussed above in conjunction with claim 50. Claim 51 further recites "wherein providing electrical energy includes: positioning a first electrode and a second electrode in sublingual positions within such a patient's oral cavity such that the second electrode is located in a position posterior relative to the first electrode, and applying an electrical stimulation via the first electrode and the second electrode so as to deliver electrical energy to a patient in an anterior-to-posterior direction or a posterior-to-anterior direction".

In contrast, Meer teaches positioning first electrode (12) in contact with a user's sublingual mucosa on one side of the user's frenulum and positioning second electrode (14) in contact with the sublingual mucosa on the opposite side of the frenulum. (Meer at column 4, lines 38 - 47.) Meer further teaches applying electrical stimulation pulses to these electrodes to stimulate the genioglossus muscle laterally (i.e., from one side of the genioglossus muscle to the other side of the genioglossus muscle). (*Id.* at column 6, lines 34 - 39.) Halstrom fails to provide any teaching related to electrode placement.

It is respectfully submitted that one of ordinary skill in the art would not arrive at a method for delivering electrical stimulation in the anterior-to-posterior or the posterior-to-anterior directions from the teachings of Meer and/or Halstrom. For these reasons, the rejection of claim 51 pursuant to 35 U.S.C. § 103(a) should be withdrawn.

Claim 52

Claim 52 depends from allowable claim 50. Thus, claim 52 is believed to be allowable for the reasons discussed above in conjunction with claim 50. Claim 52 further recites “wherein providing electrical energy includes locating a first electrode and a second electrode on a same side of a patient’s oral cavity”. As discussed above, Meer not only fails to suggest locating the first and second electrodes on the same side of a patient’s oral cavity, but instead, Meer directly teaches away from such an arrangement. Specifically, Meer teaches locating the first electrode on one side of the oral cavity (i.e., in contact with a user’s sublingual mucosa on a first side of the user’s frenulum) and the second electrode on the opposite side of the oral cavity (i.e., in contact with the sublingual mucosa on the opposite side of the frenulum). (Meer at column 4, lines 38 - 47.) Halstrom fails to provide any teaching related to electrode placement. For these reasons, the rejection of claim 45 pursuant to 35 U.S.C. § 103(a) should be withdrawn.

Claim 53

Claim 53 depends from allowable claim 50. Thus, claim 53 is believed to be allowable for the reasons discussed above in conjunction with claim 50. Claim 53 further recites “wherein providing electrical energy includes locating a first electrode and a second electrode posterior to the frenulum”. As discussed above, Meer teaches locating the first electrode in contact with a user’s sublingual mucosa on one side of the user’s frenulum and the second electrode in contact with the sublingual mucosa on the opposite side of the frenulum. (Meer at column 4, lines 38 - 47.) Because Meer teaches locating the electrodes on both sides of the frenulum and because Halstrom fails to provide any teaching related to electrode placement, it is respectfully submitted that one skilled in the art would not located the electrodes posterior to the frenulum. For these reasons, the rejection of claim 46 pursuant to 35 U.S.C. § 103(a) should be withdrawn.

Claim 54

Claim 54 depends from allowable claim 50. Thus, claim 54 is believed to be allowable for the reasons discussed above in conjunction with claim 50. Accordingly, the rejection of claim 54 pursuant to 35 U.S.C. § 103(a) should be withdrawn.

Claim 56

Claim 56 depends from allowable claim 50. Thus, claim 56 is believed to be allowable for the reasons discussed above in conjunction with claim 50. Accordingly, the rejection of claim 56 pursuant to 35 U.S.C. § 103(a) should be withdrawn.

B. Rejection Under 35 U.S.C. 103(a) over U.S. Patent Number 5,190,053 to Meer in view of U.S. Patent Number 5,365,945 to Halstrom in further view of U.S. Patent Number 4,414,982 to Durkan.

The Examiner has rejected claims 48 and 55 as being unpatentable over Meer in view of Halstrom, as applied to claims 43 - 47, 49 - 54, and 56 above, and in further view of Durkan. As will be discussed in more detail below, Applicant respectfully submits that the Examiner has failed to prove that, despite the differences between the prior art and the claimed invention, one skilled in the art would find it obvious to modify or combine the prior art in order to create the invention recited in claims 48 and 55. Accordingly, it is requested that the rejection of claims 48 and 55 be reversed.

Claim 48

The Examiner held that Meer and Halstrom teach the apparatus as recited in claim 43; however, the Examiner further held that Meer and Halstrom fail to teach a means for providing a positive pressure to an airway 22. The Examiner stated that “it would have been obvious to one skilled in the art to modify the Meer and Halstrom apparatus”, as described with respect to claim 43, “with the airway of Durkan to supply oxygen to a patient substantially throughout the duration of inspiration.”

Claim 48 depends from allowable claim 43 which recites a system having both an electromuscular stimulation means and a mandibular positioning means. Claim 48 further recites “means for providing a positive pressure to an airway of such a patient”. As discussed above, it

is believed that it would not have been obvious to one skilled in the art to combine Meer and Halstrom to obtain a system comprising both an electromuscular stimulating means and a mandibular positing means; specifically because Meer teaches away from such a combination. Durkan fails to counter the teachings of Meer away from such a combination.

The Examiner has failed to provide an explicit rationale explaining why, one of ordinary skill in the art would combine the respirator apparatus of Durkan with either the electromuscular stimulation means of Meer or the mandibular positioning device of Halstrom. Both Meer and Halstrom are directed to devices for treating sleep apnea. Durkan, on the other hand, does not teach a device used to treat apnea. In contrast, Durkan discloses a respirator apparatus for providing intermittent demand oxygen flow and/or for detecting apneic events. (See Durkan at column 1, lines 5 - 9.) Durkan teaches a device/system in which a large volume of oxygen is supplied to a patient's airway for a short period of time at the early stage of inspiration. (*Id.* at column 8, lines 42 - 55.) With the Durkan device/system, the amount of oxygen that is wasted during inspiration, as compared to prior art devices, is allegedly reduced. Durkan does not suggest that this short burst of oxygen can be used to keep open an airway or to reopen an already closed airway (i.e., Durkan fails to teach that the short burst of oxygen can be used to treat a sleep apnea). In contrast, Durkan merely teaches the breathing cycle is monitored and, if an apneic event is detected, an alarm is activated. (*Id.* at column 13, line 61 - column 14, line 15.)

Because the Durkan device does not treat sleep apnea, but instead merely detects apneic events, one of ordinary skill in the art would not have been motivated to combine this device with the Meer device. For example, the Meer device already incorporates sensors (54) for monitoring inspiratory associated conditions and detecting apneic events. (See Meer, column 6, lines 16 - 28 and lines 48 - 58.) Thus, one of ordinary skill in the art would not be inclined to combine Durkan's monitoring capability with the Meer device.

Likewise, there is no motivation to combine the detection features of Durkan with the Halstrom appliance because the amount of mandibular advancement provided by the Halstrom appliance is not adjusted in response to detecting the occurrence of an apneic event (i.e., the Halstrom device has no use for an apnea detection). Furthermore, Durkan fails to teach or suggest that the breathing gas can be delivered via an oral appliance. In contrast, Durkan teaches

that a nasal cannula, nasal prongs, or a mask is used to deliver breathing gas to a patient. (Durkan at column 3, lines 54 - 58.)

For these reasons, it is respectfully submitted that it would not be apparent to one of ordinary skill in the art to combine the teachings of Meer, Halstrom, and Durkan to obtain the system recited in claim 48. Accordingly, the rejection of claim 48 pursuant to 35 U.S.C. § 103(a) should be withdrawn.

Claim 55

The Examiner rejected claim 55 “because the apparatus of Meer in view of Halstrom in view of Durkan as applied to claim 48 above performs the method steps as claimed”. Claim 55 depends from claim 50 and further comprises “providing a positive pressure to an airway of such a patient”.

As discussed above in conjunction with claim 50, one of ordinary skill in the art would not find it obvious to combine the teachings of Meer with the teachings of Halstrom to obtain a system for treating a breathing disorder comprising an electromuscular stimulating means and a mandibular positioning means. Likewise, one skilled in the art would not find it obvious to combine the teachings of Meer and Halstrom to obtain the method for treating sleep apnea in which electrical energy is provided to a sublingual location of a patient and a position of such a patient’s mandible is controlled relative to an upper dentition of such a patient. It is further submitted that Durkan fails to teach or suggest such a combination.

Furthermore, as discussed in conjunction with claim 48, there is no motivation to combine Durkan with either Meer or Halstrom. For these reasons, it is believed that claim 55 is allowable. Accordingly, the rejection of claim 55 pursuant to 35 U.S.C. § 103(a) should be withdrawn.

C. Whether claims 57 - 58, and 60 were properly rejected under 35 U.S.C. § 103(a) as being unpatentable over Meer in view of *Aller*?

The Examiner has rejected claims 57, 58, and 60 as being unpatentable over Meer in view of *Aller*. In *Aller*, United States Court of Customs and Patent Appeals (the “Court”) held that altering the temperature and sulphuric acid concentrations of a known process was not

inventive. The Court held that “where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation”. (*Id.* at 456; citing *In re Swain et al.*, 33 C.C.P.A. (Patents) 1250, 156 F.2d 239, 70 USPQ 412; *Minnesota Mining and Mfg. Co. v. Coe*, 69 App.D.C. 217, 99 F.2d 986; *Allen et al. v. Coe*, 77 App.D.C. 324, 135 F.2d 11.) The Court further held that “it being apparent that the claimed process is merely different in degree and not in kind from the reference process, and that the criticality of the claimed ranges has not been shown, the decision of the Board of Appeals is affirmed.” (*Id.* at 459.)

In the instant case, the Examiner stated that “Meer teaches first and second electrodes 12, first and second support members 24, respiratory sensor (Col. 2 ll. 56 - 66), stimulation through at least a portion of inspiration (Col. 6 ll. 44 - 47), and support member coupling 18 and 20.” The Examiner further stated that Meer does not teach “posterior to anterior or anterior to posterior electrode placement and stimulation, nor stimulation start time prior to onset of inspiration.” However, the Examiner cited *Aller* as holding “that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.”

It is respectfully submitted that the invention recited in claims 57, 58, and 60 is different in kind from that disclosed in Meer (i.e., the general conditions of the invention recited in claims 57, 58, and 60 are not disclosed in Meer). Furthermore, it is submitted that the invention recited in claims 57, 58, and 60 is not merely an optimum or workable range of the device disclosed in Meer.

As previously discussed, Meer discloses an intra-oral, sublingual electrode device having electrodes in contact with a user’s sublingual mucosa on either side of the user’s frenulum. (Meer at column 4, lines 38 - 47.) Hence, electrical current flows laterally through the user’s genioglossus muscle when electrical pulses are applied to the electrodes (*Id.* at column 6, lines 29 - 39.) Due to this electrode arrangement, any stimulation pattern applied to the Meer device will result in electrical current flowing laterally across the genioglossus muscle. Thus, experimentation with various stimulation patterns will not result in posterior-to-anterior or anterior-to-posterior current flow.

Unlike *Aller* in which the claimed process was identical to the prior art process except for altering the temperature and acid concentration, it is respectfully submitted that the claims 57,

58, and 60 recite an invention that is different in kind from Meer, and not merely different in degree. Specifically, current applied to the claimed device flows posterior-to-anterior or anterior-to-posterior within the user's oral cavity; whereas current applied to the Meer device flows laterally across the genioglossus muscle. Thus regardless of the specific stimulation pattern is applied to the Meer device, current will not flow posterior-to-anterior or anterior-to-posterior within the user's oral cavity as recited in claims 57, 58, and 60.

It is respectfully submitted that the Examiner has failed to provide any support for the conclusory statement that rearrangement of the electrodes such that the second electrode is disposed posterior to the first electrode (as in the claimed invention) is merely an optimum or workable range found through experimentation by one skilled in the art with electrodes disposed on opposite sides of the user's frenulum (as disclosed by Meer). Additionally, the Examiner has failed to provide any support for the conclusory statement that applying electrical stimulation to the electrodes at a time prior to onset of inspiration (as in the claimed invention) is merely an optimum or workable range found through experimentation by one skilled in the art with applying electrical stimulation to the electrodes in response to the inspiratory efforts of a patient and/or in response to an indication of respiratory distress (Meer at column 6, lines 48 - 58).

For these reasons, it is believed that claims 57, 58, and 60 are allowable. Accordingly, the rejection of claims 57, 58, and 60 pursuant to 35 U.S.C. § 103(a) should be withdrawn.

Conclusion

In view of the foregoing, it is respectfully submitted that the rejections of claims 43 - 47, 49 - 54, and 56 under 35 U.S.C. § 103(a) in view of Meer and Halstrom, the rejection of claim 48 and 55 under 35 U.S.C. § 103(a) in view of Meer, Halstrom, and Durkan, and the rejection of claims 57, 58, and 60 under 35 U.S.C. § 103(a) in view of Meer and *Aller* are improper, and all of the pending claims are allowable. Appellant therefore respectfully urges the Board to reverse the Examiner's final rejections of these claims.

Payment of \$510.00 to cover the large entity fee for filing an Appeal Brief Under 37 C.F.R. §41.37. The Commissioner for Patents and Trademarks is hereby authorized to charge any additional fees which may be required to Deposit Account No. 50-0558. Please refund any overpayment to Deposit Account No. 50-0558.

Respectfully submitted,

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APPENDIX A - PENDING CLAIMS

Claims 1-42. (Cancelled)

Claim 43

A system for treating a breathing disorder comprising:
electromuscular stimulating means for providing electrical energy to a sublingual
location of a patient; and
mandibular positing means for controlling a position of such a patient's mandible
relative to an upper dentition of such a patient.

Claim 44

The system of claim 43, wherein the electromuscular stimulating means includes
positioning means for locating a first electrode and a second electrode in sublingual positions
within a patient's oral cavity such the second electrode is located in a position posterior to the
first electrode to deliver the electrical energy in an anterior-to-posterior direction or a posterior-
to-anterior direction.

Claim 45

The system of claim 43, wherein the electromuscular stimulating means includes
positioning means for locating a first electrode and a second electrode on a same side of a
patient's oral cavity.

Claim 46

The system of claim 43, wherein the electromuscular stimulating means includes
positioning means for locating a first electrode and a second electrode posterior to the frenulum.

Claim 47

The system of claim 43, wherein the mandibular positing means comprises:

- a first member adapted to engage a structure associated with a patient's upper dentition;
- a second member adapted to engage a structure associated with such a patient's mandible; and
- means for limiting movement of the first member relative to the second member, thereby controlling a position of such a patient's mandible relative to the upper dentition.

Claim 48

The system of claim 43, further comprising means for providing a positive pressure to an airway of such a patient.

Claim 49

The system of claim 43, wherein the electromuscular stimulating means includes:

- respiration detecting means for detecting an inspiratory phase and an expiratory phase of a patient; and
- means for controlling a delivery of electrical energy such that electrical stimulation occurs at a stimulation start time prior to onset of the inspiratory phase and continues through at least a portion of the inspiratory phase.

Claim 50

A method of treating a breathing disorder comprising:

- providing electrical energy to a sublingual location of a patient; and
- controlling a position of such a patient's mandible relative to an upper dentition of such a patient.

Claim 51

The method of claim 50, wherein providing electrical energy includes:

positioning a first electrode and a second electrode in sublingual positions within such a patient's oral cavity such that the second electrode is located in a position posterior relative to the first electrode; and

applying an electrical stimulation via the first electrode and the second electrode so as to deliver electrical energy to a patient in an anterior-to-posterior direction or a posterior-to-anterior direction.

Claim 52

The method of claim 50, wherein providing electrical energy includes locating a first electrode and a second electrode on a same side of a patient's oral cavity.

Claim 53

The method of claim 50, wherein providing electrical energy includes locating a first electrode and a second electrode posterior to the frenulum.

Claim 54

The method of claim 50, wherein controlling a position of such a patient's mandible comprises:

engaging a first member with a structure associated with a patient's upper dentition;
engaging a second member with a structure associated with such a patient's mandible;

and

limiting movement of the first member relative to the second member, thereby controlling a position of such a patient's mandible relative to the upper dentition.

Claim 55

The method of claim 50, further comprising providing a positive pressure to an airway of such a patient.

Claim 56

The method of claim 50, wherein providing electrical energy includes:
detecting an inspiratory phase and an expiratory phase of a patient; and
controlling delivery of electrical energy such that electrical stimulation occurs at a stimulation start time prior to onset of the inspiratory phase and continues through at least a portion of the inspiratory phase.

Claim 57

An intraoral electromuscular stimulation device adapted to provide intraoral electrical stimulation to a patient, the device comprising:
a first electrode;
a first support member adapted to support the first electrode in a sublingual location within a patient's oral cavity;
a second electrode;
a second support member adapted to support the second electrode in a sublingual location within such a patient's oral cavity, wherein the first support member and the second support member are configured and arranged such that the second electrode is disposed in a position posterior relative to the first electrode;
a sensor adapted to detect a respiratory parameter of such a patient and to output a signal indicative thereof; and
a control unit operatively coupled to the sensor, the first electrode and the second electrode, wherein the control unit (1) receives the signal from the sensor and distinguishes between inspiration and expiration of such a patient based thereon, (2) initiates an electrical stimulation of such a patient in an anterior-to-posterior or posterior-to-anterior direction via the first and the second electrodes at a stimulation start time between 100-200 ms prior to onset of inspiration, and (3) continues stimulation through at least a portion of inspiration.

Claim 58

The device of claim 57, wherein the first support member and the second support member are coupled to one another.

Claim 59 (Cancelled).

Claim 60

An intraoral electromuscular stimulation device adapted to provide intraoral electrical stimulation to a patient, the device comprising:

- a first electrode;
- a first support member adapted to support the first electrode in a sublingual location within a patient's oral cavity posterior to a frenulum and generally proximate to one of a first molar, a second molar, and a third molar of such a patient;
- a second electrode;
- a second support member adapted to support the second electrode in a sublingual location within such a patient's oral cavity and posterior relative to the first electrode, wherein the first support member and the second support member are configured and arranged such that the second electrode is disposed in a position posterior relative to the first electrode;
- a sensor adapted to detect a respiratory parameter of such a patient and to output a signal indicative thereof; and
- a control unit operatively coupled to the sensor, the first electrode and the second electrode, wherein the control unit (1) receives the signal from the sensor and distinguishing between inspiration and expiration of such a patient based thereon, (2) initiates an electrical stimulation of such a patient in an anterior-to-posterior or posterior-to-anterior direction via the first and second electrodes at a stimulation start time prior to onset of inspiration, and (3) continues stimulation through at least a portion of inspiration.

APPENDIX B—EVIDENCE

NONE

APPENDIX C—RELATED PROCEEDINGS

NONE